

### REMARKS

The claims have been amended in order to overcome several of the grounds of rejection set forth at pages 2 and 3 of the Official letter. Inasmuch as no new matter is embodied in the proposed amendments, entry thereof is respectfully requested.

The rejection of claim 1 on the basis that "it is not clear what standard of comparison "enhance" is being used against" is respectfully traversed. The rules of syntax make it clear that the "standard of comparison" is the case in which the pretreatment is not utilized. Accordingly, withdrawal of this ground of rejection is respectfully requested.

The rejection of the claims under 35 USC 103 as unpatentable over Goldberg in view of Darouiche is respectfully traversed. Regarding the primary reference to Goldberg, the Examiner states:

*"---(Goldberg) does not disclose that the device surface is hydrolyzed, but because the solution of the applicant and the solution of '379 are the same (same monomers, unlimited pH), it would be inherent that the hydrolysis would take place---" (emphasis added).*

The Examiner's attention is directed to the fact that the respective solutions are not the same inasmuch as Goldberg does not disclose the use of "unlimited pH". Rather, Goldberg discloses no pH values whatsoever. The Examiner is not permitted to read a limitation or specific disclosure into a reference simply on the basis that the reference does not discuss the subject matter thereof.

The Examiner further states with respect to Goldberg:

*"---(Goldberg) does not disclose that the device surface is hydrolyzed, but because the solution of the applicant and the solution of '379 are the same (same monomers, unlimited pH), it would be inherent that the hydrolysis would take place---*" (emphasis added).

The Examiner's attention is directed to the fact that the present claims are not drawn to "hydrolyzing" a surface. If the Examiner intended to state that any result produced by the claimed method is also inherently produced by Goldberg, it is respectfully pointed out that the respective solutions are not identical for the reasons set forth above with respect to "unlimited pH".

It is apparently the Examiner's position that the deficiencies of the primary reference are supplied by the secondary reference to Darouiche ('283). Thus, the Examiner states:

*"---'283 teaches that adding an alkanizing agent (to a pH of about 12) such as sodium hydroxide to a solution of an antimicrobial composition (such as antibiotics) that is to be applied to a silicone medical implant enhances the reactivity of the antimicrobial with the silicone of the medical implant (3:17-4:67; 6:14-18; Example 1)---"* (emphasis added).

The Examiner's attention is directed, however, to the fact that, in the claimed method, the "alkalizing" agent is not present to enhance the bond between the antimicrobial and the silicone surface, but rather, to enhance the graft polymerization of the polymerizable substance to the silicone surface. Inasmuch as the secondary reference is not concerned with the graft polymerization of any thing to the treated surface, it cannot be said to render anything connected with graft polymerization obvious. Thus, the Examiner has not supplied a prior art teaching of a critical aspect of the invention, namely, the activation of the silicone surface to enhance the graft polymerization at the surface.

Recognizing this defect in reasoning, the Examiner further states:

*"---The applicant has argued that '283 does not recognize that pH affects the graft polymerization of monomers to polysiloxane surfaces. However, this effect is inherent to the use of sodium hydroxide and a basic pH---"* (emphasis added).

It is respectfully submitted that it is not open to the Examiner to simply state that a missing element in the chain of evidence required to render a claimed invention obvious is “inherent” without supporting documentation. It is not seen how this ground of rejection can be maintained without a reference to support the Examiner’s contention that this effect is inherent to the use of sodium hydroxide and a basic pH.

The Examiner’s reasoning fails to take into account, however, that is based upon a hindsight reconstruction of the invention utilizing the applicants’ disclosure as a template for selecting isolated disclosures from two separate references containing disparate and unrelated teachings and combining them to arrive at the claimed invention in the absence of any suggestion in the references themselves that they can be so combined.

A legal conclusion of patent invalidity for obviousness must be supported by findings on the four factual inquiries set forth in *Graham v. John Deere Co.*, [383 U.S. 1, 148 USPQ 459 (1966)]. The legal conclusion of invalidity for obviousness depends on four factual inquiries identified by *Graham v. John Deere Co.* as concerning (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness.

In the present case the Examiner must conduct a *Graham* analysis as the danger increases that “the very ease with which the invention can be understood may prompt one to ‘fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher,’” *In re Dembiczak*, 175 F.3d 994, 50 USPQ2d 1614 (Fed. Cir. 1999).

In order to justify a combination of references, it is necessary not only that it be physically possible to combine them, but also that the art should contain something to suggest the desirability of doing so. *Ex parte Walker*, 135 USPQ 195; *Ex parte Fleischmann*, 157 USPQ 155. The prior art cannot be combined as if appellant’s invention was included therein

as a part of the knowledge possessed by one of ordinary skill in the art. In combining references, the prior art references themselves must suggest their being combined so as to render the claimed invention obvious to one skilled in the art; and resort must not be had to applicant's own disclosure and the utilization of hindsight for the guiding hand that dictates the combination of references.

It is further well settled that the prior art itself must suggest the problem sought to be solved by the claimed invention before it can be said to suggest or disclose its solution. In re Shaffer, 108 USPQ 326; In re Aufhauser, 158 USPQ 351; US v. Adams 148 USPQ 479; In re Nomiya, 184 USPQ 607. The Examiner herein has not cited prior art that recognizes the problem solved by the claimed invention, namely, the strengthening of the siloxane/graft polymer bond.

Any analysis of obviousness must necessarily begin in the text of section 103, with the phrase "at the time the invention was made." For it is this phrase that guards against entry into the "tempting but forbidden zone of hindsight," [see *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861,873; 228 USPQ 90,98 (Fed. Cir. 1985), overruled on other grounds by *Nobel-pharma AB v. Implant Innovations, Inc.*, 141 F. 3d1059, 46USPQ2d 1097 (Fed. Cir, 1998)], when analyzing the patentability of claims pursuant to that section.

Measuring a claimed invention against the standard established by section 103 requires the often difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. See, e.g., *W.L Gore & Assoc., Inc. y. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 UPSQ 303, 313 (Fed. Cir 1983).

The present state of the patent law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.

See, e.g., *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F. 3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998,) (describing “teaching or suggestion or motivation [to combine]” as an “essential evidentiary component of an obviousness holding”) *In re Rouffet*, 149 F.3d 1350, 1359; 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) (“the Board must identify specifically---the reasons one of ordinary skill in the art would have been motivated to select the references and combine them”); *In re Fritch* 972 F.2d 1260, 1265; 23 USPQ2d 1780, 1783 (Fed cir. 1992) (examiner can satisfy burden of obviousness in light of combination “only by showing some objective teaching [leading to the combination]”); *In re Fine*, 837 F.2d 1071, 1075; 5 USPQ2d 1596, 1600 (Fed Cir. 1988) (evidence of teaching or suggestion “essential” to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins*, 776 F.2d 281, 297, 227 USPQ 657, 667 (Fed Cir. 1985) (district court’s conclusion of obviousness was error when it “did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination”). See also *Graham* 383 U.S. at 18, 148 USPQ at 467 (“strict observance” of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor’s disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. See, e.g., *Inteconnect Planning Corp. v. Feil*, 774 F.2d 1132 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) (“The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time.”). In this case, the Board(Examiner) has obviously fallen into the hindsight trap.

We have noted that evidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved, see *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573; 37 USPQ2d 1626, 1630 (Fed. Cir. 1996), *Para-Ordinance Mfg. v. SGS Imports Intern., Inc.*, 73 F.3d 1085, 1088; 37 USPQ2d

1237, 1240 (Fed. Cir. 1995), although “the suggestion more often comes from the teachings of the pertinent references,” *Rouffet*, 149 F.3d at 1355, 47 USPQ2d at 1456. The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be clear and particular. See, e.g., *C. R. Bard*, 157 F.3d at 1352; 48 USPQ2d at 1232. Broad conclusory statements regarding the teachings of multiple references, standing alone, are not “evidence.” E.g., *McElmurry V. Arkansas Power & Light Co.*, 995 F.2d 1576, 1578; 27 USPQ2d 1129, 1131 (Fed. Cir. 1993) (“Mere denials and conclusory statements, however, are not sufficient to establish a genuine issue of material fact.”); *In re Sichert*, ‘566 F.2d 1154, 1164, 196 USPQ ~209, 217 (CCPA 1977).

In a recent (nonprecedential) decision the USPTO Board of Appeals and Patent Interferences *Ex parte Metcalf* [67 USPQ2d 1633, (2003)] recently considered the following situation: The examiner proposed to combine teachings of Paroutaud with those of Murry “because in a reproduction of music, each microphones [sic] *could* detect the sound of each instrument in the musical instrument and record each instrument onto a separate channel. Also, volume of each signal *could* be controlled and amplified separately to drive each instrument transducers [sic].” The Board held that Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination, citing *Carella v. Starlight Archery and Pro Line Co.*, 804 F.2d 135, 140, 231 USPQ 644, 647 (Fed. Cir. 1986) (citing *ACS Hosp. Syss., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984) and that the factual inquiry whether to combine references must be thorough and searching, citing *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351-52, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001). The Board went on to state that this factual question cannot be resolved on subjective belief and unknown authority, citing *In re Lee*, 277 F.3d 1338, 1343-44, 61 USPQ2d 1430, 1434 (Fed. Cir. 2002); that it must be based on objective evidence of record, citing *Id.* at 1343, 61 USPQ2d at 1434. The

Board further noted that the U.S. Court of Appeals for the Federal Circuit has stated that “[t]he mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.” *In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992) (citing *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984)). The Board noted that, although this statement is couched in terms of modifying the prior art, “we hold that a similar one applies to combining teachings found in the prior art. Specifically, the mere fact that teachings found in the prior art could be combined as proposed by an examiner does not make the combination obvious ‘absent some teaching, suggestion or incentive supporting the combination, citing *Carella*, 804 F.2d at 140, 231 USPQ at 647 (citing *ACS Hosp. Sys., Inc.*, 732 F.2d at 1577, 221 USPQ at 933). In the instant appeal, the examiner fails to identify any such teaching, suggestion, or incentive to support his proposed combination. Therefore, we reverse the rejection of claims 1, 2, 4-10, 12-15, 17-19, and 21-55 as obvious over the combination of Murry and Paroutaud”.

It is clear that the authorities are unanimous in holding that it is impermissible to use the claimed invention as an instruction manual or “template” to piece together isolated disclosures and teachings of the prior art so that the claimed invention may be rendered obvious. A rejection based on § 103 must rest on a factual basis, with the facts being interpreted without hindsight reconstruction of the invention from the prior art. In making this evaluation, the examiner has the initial duty of supplying the factual basis for the rejection he advances. He may not, because he doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis. See *In re Warner*, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968). Since there is no factual basis in the prior art relied on which supports the proposed combination thereof, and it is apparent that the examiner’s conclusion of obviousness is based on hindsight reconstruction of the claimed invention from isolated disparate teachings in prior

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art which is not concerned with the problem sought to be solved by the claimed invention, this  
ground of rejection is not sustainable.

Accordingly, withdrawal of this ground of rejection is respectfully requested.

Respectfully submitted,

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